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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,448	04/16/2004	Greg Collier	007193-4	4190

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EXAMINER	
STANDLEY, STEVEN H	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/826,448	COLLIER ET AL.	
	Examiner	Art Unit	
	Steven H. Standley	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, and 19 drawn to a nucleic acid, classified in class 536, subclass 23.5.

II. Claims 5-8, and 20 drawn to a polypeptide, classified in class 530, subclass 350.

III. Claims 9-10, and 18 drawn to an antibody to the polypeptide and a method of detecting the polypeptide, classified in class 530, subclass 387.1.

IV. Claim 11 and 13 (in part) and 16, drawn to a method of modulating expression of a molecule, classified in class 435, subclass 7.2.

V. Claim 12 and 13 (in part) and 15, drawn to a method of modulating activity of a molecule, classified in class 435, subclass 7.2.

VI. Claim 14, drawn to a method of treating by administration of a polypeptide, classified in class 514, subclass 2.

VII. Claim 17 drawn to a composition that modulates the expression or activity of a molecule, classified in class 514, subclass 1.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> products, restriction is deemed to be proper because these products constitute

patentably distinct inventions for the following reasons. Groups I-III are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the protein of Group II can be prepared by processes which are materially different from recombinant DNA expression of Group I, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group I can be used other than to make the protein of Group II, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group II can be used in materially different methods other than to make the antibody of Group III, such as in therapeutic or diagnostic methods (e.g., in screening). Finally, although the antibody of Group III can be used to obtain the DNA of Group II, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods.

Inventions I-III and IV-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acid can be used to make the polypeptide for the methods of groups IV-VI, it can also be used for in situ hybridization in a diagnostic. The polypeptide of Group II can also be used in a materially different process than the methods of groups IV-VI. For instance, it can be used in a method of determining the molecular weight of other proteins on an SDS-PAGE gel. The antibody of Group III can be used in methods other than those of

Groups IV-VI. For instance the antibody can be used in a method of determining the molecular weight of other proteins on an SDS-PAGE gel.

Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons: Groups IV-VI are distinct methods with different goals and that administer different compounds or polypeptides. For instance, Group IV is a method of modulating the expression of one of the claimed polypeptides by administering a compound whereas Group V is a method of modulating the *activity* of the polypeptide. Thus Groups IV and V have different goals and administer different compounds. Group VI is a method of treating a patient by *administration* of the polypeptide of Groups IV and V. Thus Group VI is directed at a different goal and administers the polypeptide itself and not compounds that modulate the activity or expression of said polypeptide. Therefore a search and examination of the methods of groups IV-VI together or in any combination would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups VII compared to Groups I-III are directed to products that are distinct both physically and functionally,

and are not required one for the other. Group I is directed to a nucleic acid while Group VII is directed to a pharmaceutical composition that modulates expression or activity of the protein encoded by the nucleic acid of Group I. However, the nucleic acid of group I is not required to make the compound of group VII. The compound can be made by isolating the natural polypeptide and determining the compound of group VII's binding and modulatory characteristics. Furthermore, the polypeptide of Group II can be used for products other than the compound of Group VII, such as making the antibody of Group III. The antibody of Group III is not required to identify the compound of Group VII. Therefore, a search and examination of all products in one patent application would result in an undue burden, since the searches for the three methods are not co-extensive, the classification is different, and the subject matter is divergent.

Inventions VII and IV-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the processes used, methods of identifying compounds that modulate activity or expression, can be used to identify compounds that modulate activity or expression of NMDA receptors as well.

Inventions VII and VI are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the

process administers the polypeptide target of the pharmaceutical composition of group VII. Thus, Group VI cannot administer the compound of Group VII.

Furthermore, within group I restriction to one of the following inventions is required under 35 USC 121:

The inventions are directed to different nucleic acids identified as SEQ ID NO: 1, 2, 3 (which encodes the polypeptide of SEQ ID NO: 4), 5, 6, 7, 8, and 9. The claims encompass several structurally unrelated genes. For instance, absent evidence to the contrary the genes have different sequences and code for structurally and functionally different proteins.

Applicant is advised that this is not a requirement to elect a species. Rather, this is a second restriction requirement superimposed upon the requirement to elect from groups I-VII. In order to be fully responsive, Applicant must elect one group from I-VII and should Applicant elect group I, one gene from those listed above from within the elected group is also required.

Furthermore, within group II-III restriction to one of the following inventions is required under 35 USC 121:

The inventions are directed to different polypeptides or antibodies thereto encoded by nucleic acids identified as SEQ ID NO: 1, 2, 3 (which encodes the polypeptide of SEQ ID NO: 4), 5, 6, 7, 8, and 9. The claims encompass several structurally unrelated genes. For instance, absent evidence to the contrary the genes have different sequences and code for structurally and functionally different proteins.

Applicant is advised that this is not a requirement to elect a species. Rather, this is a second restriction requirement superimposed upon the requirement to elect from groups I-VII. In order to be fully responsive, Applicant must elect one group from I-VII and should Applicant elect group II-III, polypeptide or antibody thereto from those listed above from within the elected group is also required.

Furthermore, within groups IV-X restriction to one of the following inventions is required under 35 USC 121:

The inventions are directed to methods using 'biological molecules' indicated as AGT-119, AGT-120, AGT-121, AGT-122, AGT-422, AGT-423, AGT-504 (or italicized *AGT-119, AGT-120, AGT-121, AGT-122, AGT-422, AGT-423, AGT-504*). The claims encompass several structurally unrelated genes, nucleic acids or polypeptides. For instance, absent evidence to the contrary the genes have different sequences and code for structurally and functionally different proteins.

Applicant is advised that this is not a requirement to elect a species. Rather, this is a second restriction requirement superimposed upon the requirement to elect from groups I-VII. In order to be fully responsive, Applicant must elect one group from I-VII and should Applicant elect group IV-X, the polypeptide or nucleic acid or 'biological molecule' from those listed above from within the elected group is also required.

In re Ochiai

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.
11/01/06